Remarks

The Office Action mailed September 19, 2002 has been received and reviewed. Applicants note the filing of a Request for Continued Examination with this Amendment. Claims 1, 5, 6, 9-15, and 28-36 are pending. Claims 30-36 were withdrawn from consideration and are canceled without prejudice or disclaimer herein. New claims 37-39 are presented herein. Claims 1, 5, 6, 9-15, 28 and 29 stand rejected. The application is to be amended as reflected herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Substitute Specification previously filed October 23, 2001

The Examiner previously objected to the specification as allegedly being full of terms which are not clear, concise and exact. Applicants have reviewed the specification and, pursuant to 37 C.F.R. §§ 1.121 and 1.125 (as amended to date) please enter the substitute specification in clean form and including paragraph numbers **[0001]** through **[0044]** attached hereto as Appendix A. A marked-up substitute specification to clearly identify amendments to the specification as required by 37 C.F.R. § 1.121(b)(3)(iii) is attached hereto as Appendix B.

Applicants note that the substitute specification previously filed October 23, 2001, was not entered. (Paper No. 10, page 2). Applicants re-submit herewith the previously filed substitute specification and submit that no new matter is added therein. Reconsideration and entry of the substitute specification is requested.

35 U.S.C. §112, first paragraph

Claims 1, 5-6, 9-15 and 28-29 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse the rejection.

Specifically, it was stated that the specification, while being enabled for the *in vitro* induction of non-responsiveness of MHC-matched clonal T cells to a defined antigen when dexamethasone-treated dendritic cells have been loaded with the same defined antigen, does not provide enablement for *in vivo* or *in vitro* induction of non-responsiveness of polyclonal T cells to any undefined antigen or the *in vivo* induction of non-responsiveness when an "unwanted T-cell response" is ongoing. Further, it was stated that it appeared that applicants were arguing that the invention of the instant claims function through a previously undescribed mechanism.

The description in the response filed October 29, 2001, does not involve an undescribed mechanism, but rather is discussed throughout the Specification, for example, page 3, line 19

through page 5, line 20. Further, the declaration filed herewith[1], demonstrates that addition of a glucocorticoid hormone to immature DC results in a decreased proliferative response and a decrease in IFN-γ production by BALB/c splenocytes stimulated by these DCs. *In vivo* treatment with DEX pretreated mature DC decreased the allogeneic ml response as shown by a reduced IFN-γ production *in vitro* and a reduction in number of IFN-γ producing effector cells when the response was compared to mice pretreated with mature DC, both after sc or iv injection of the DEX pretreated DCs, but even more after *in vivo* treatment with the alternatively activated (DEX-LPS) DC. Thus, pretreatment of recipients with DC leads to a significantly prolonged skin graft survival.

The declaration confirms and extends the practical use of alternatively activated DC for modulation of the alloimmune response and shows that these can induce a prolonged skin graft survival even in a complete MHC incompatible donor-recipient combination. Reconsideration and withdrawal of the rejection is requested.

Claims 1, 5-6, 9-15 and 28-29 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject mater which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the applicants have not disclosed any glucocorticoid other than dexamethasone.

Applicants respectfully submit that independent claim 1 as filed, included the element, "a glucocorticoid hormone". Written description requirement issues most often come "into play where claims not presented in the application when filed are presented thereafter." *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1114 (CAFC 1991). As previously stated, glucocorticoids are a well known class of adrenocorticotropic hormones. The previous statement that glucocorticoids are discussed generally as a class with respect to physiology, biological activity, side effects, drug interactions, absorption, fate and excretion, and therapeutic uses, suggested that tremendous uniformity exists among the class of glucocorticoids. Thus, because of such uniformity within the class of glucocorticoids, applicants respectfully submit that one of skill in the art would understand that dexamethasone is merely an exemplary glucocorticoid and that the disclosure is applicable to all glucocorticoids. Reconsideration and withdrawal of the rejection is respectfully requested.

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[1] An executed copy of the declaration will be forwarded upon receipt.

Further, independent claim 1 was amended to replace "glucocorticoid hormone" with "means for reducing IL-12p40 production by said dendritic cell" and independent claim 13 was amended to replace the term "glucocorticoid hormone" with "means for inducing said said dendritic cell to secrete IL-10". Support for the amendment can be found in the Specification, for example, page 4, lines 20-25; page 3, lines 19-36; and page 10, lines 22-36. Reconsideration and withdrawal of the rejection is respectfully requested.

New Claims

New claim 37 is presented herein and is substantially the same as previously canceled claim 7. Applicants submit that claim 7 was inadvertently canceled in the last response and does not include new matter. The Examiner noted that claim 7 was within the group of claims elected for prosecution. (Paper No. 13, page 2). New claims 38 and 39 are dependent claims which define an element of the independent claims as being "dexamethasone". Support for claims 38 and 39 can be found throughout the Specification.

Conclusion

In the event questions remain after consideration of these amendments, the Office is kindly requested to contact applicant's attorney at the number given below.

Respectfully submitted,

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Enclosures: Appendices A and B